DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region m49800

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6010

November 21, 2000

Certified Mail
Return Receipt Requested

WARNING LETTER

Sidney Bates, Owner
Bates Jersey Corporation
c/o Americair
3180 Redhill Avenue
Suite B
Costa Mesa, CA 92626-3448

File No.: 01-NWJ-06

Dear Mr. Bates:

During an inspection of your facility located at 129 D Gaither Drive, Mount Laurel, NJ, on September 27 & 29, 2000, our investigators documented serious deviations from Current Good Manufacturing Practice Regulations (CGMP), Title 21, Code of Federal Regulations, Parts 210 & 211.

These deviations from CGMP cause your drug product, Oxygen USP, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act), and misbranded within the meaning of Sections 502(b)(2) and 502(o) of the Act.

Specifically, your product is considered adulterated due to the following violations:

- Failure to assay the filled high pressure cylinders of Oxygen USP for identity and strength prior to release.
- Failure to establish written procedures designed to assure that the drug product conforms to appropriate standards of identity, strength, quality, and purity.
- Failure to establish batch production and control records for each batch of drug product (Oxygen) produced, including documentation that each significant step in the manufacture, processing, or holding of the batch was accomplished, including all pre-fill inspection steps for Oxygen cylinders.
- Failure to establish written procedures designed to assure that correct labels and labeling are used. This includes identification of the drug product with a lot or control number that permits determination of the history of the

manufacture and control of the batch and facilitates tracing of cylinders in the event of a product recall.

- Failure to maintain records of the periodic calibration of the oxygen analyzer and associated equipment, such as vacuum gauges.
- Failure to establish a Quality Unit with the authority to approve or reject all drug product lots, components, procedures, and specifications impacting upon drug products.
- Failure to assure that each person responsible for transfilling Oxygen USP cylinders has the training and experience necessary to perform required tasks as well as training in CGMP regulations.
- Failure to establish procedures for the receiving and handling of complaints.

Your product is considered misbranded due to the following:

- The labeling for the Oxygen USP cylinders fails to contain a statement of the quantity of the contents.
- The Oxygen USP cylinders were transfilled in an establishment that was not registered in accordance with Section 510 of the Act, and the product was not listed as required by Section 510(j) of the Act.

The above deviations are not intended to be an all-inclusive list of violations. It is your responsibility to assure that your medical gas operations and products are in compliance with the law. You should take prompt action to correct the violations and to establish procedures to prevent their recurrence. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

We have not yet received your written response that was promised at the close of the inspection on September 29, 2000. During the inspection, the General manager of the facility provided out investigators with a written commitment to cease transfilling and distribution of oxygen cylinders until your firm is in compliance with CGMP regulations. As the owner of the firm, please confirm whether your manager has the authority to cease production and whether you are still adhering to this commitment.

You should notify this office within 15 working days of receipt of this letter of the steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation that demonstrates that corrections have been made.

Your reply should be sent to the Food and Drug Administration, New Jersey District Office, 10 Waterview Boulevard, 3rd Floor, Parsippany, New Jersey 07054, Attention: Sarah A. Della Fave, Compliance Officer.

Sincerely,

Douglas I. Ellsworth
District Director
New Jersey District

cc: Charles Stehli, General Manager
Bates Jersey Corporations
d/b/a Americair South Jersey
129 D Gaither Drive
Mount Laurel, New Jersey 08054